

# Report on 2002 Institutional Annual Report on Possible Research Misconduct

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## Executive Summary

For the reporting year 2002, ORI conducted, for the third consecutive year, its electronic Internet-based system to allow institutions to access their ORI assurance record to update institutional contact information and to electronically submit their annual report.

The amount of misconduct activity—receipt of an allegation or conduct of an inquiry or investigation—reported by institutions in their 2002 Annual Report on Possible Research Misconduct increased for the fourth consecutive year.

In 2002, 99 institutions reported misconduct activities. Seventy-one of these institutions opened 83 new cases; the other institutions were still responding to allegations received earlier. New cases were opened by 50 higher education institutions, 7 research organizations, 6 independent hospitals, 5 health organizations, and 3 small businesses.

Institutions received 163 allegations. The number of allegations of fabrication, falsification, plagiarism, and “other” increased from 2002. The 83 new cases opened by the institutions resulted in 67 inquiries and 31 investigations. Some cases were closed following a preliminary assessment of the allegations or were received too late in the year to begin an inquiry.

Of the 4,127 annual reports for calendar year 2002 due for renewal, about 84 percent were returned by the March 31, 2003, deadline. This was up from about 82 percent reported for the 2001 submissions.

The effort to establish and utilize an e-mail network covering all institutions that have an active assurance continues to progress well. About 98 percent of the institutions have submitted e-mail addresses for their responsible official. The e-mail network enables ORI to quickly contact institutional officials individually or en masse. The e-mail system was used to send the initial notification of the submission of the annual report, as well as follow-up notices.

Ninety-nine percent of the responding institutions appear to have the required policy for handling allegations of scientific misconduct. Ninety-six percent of the responding institutions indicated that they have the required policies. Another 3 percent have policies on file with ORI even though they either indicated that they did not have such a policy or did not answer the pertinent question. The 59 institutions that reported they did not have the required policy were asked to establish one and send it to ORI for review.

The results of the 2002 Annual Report survey required considerable updating of the ORI assurance database which contains the names of all institutions that have an active assurance and therefore are eligible to receive PHS research support. Six hundred and fifty-two assurances were considered delinquent, including 595 institutions that did not return their Annual Report by the March 31 deadline, and 57 institutions that voluntarily withdrew their assurances rather than submit the Annual Report or submit a previously requested misconduct policy. Small businesses accounted for 62 percent of the inactivated assurances; higher education accounted for 14 percent.

The Annual Report survey continues to encounter problems with (1) the initial response rate, (2) erroneous or confusing responses regarding the availability of policies, (3) unanswered questions, and (4) ambiguous responses. ORI will address these problems through the *ORI*

*Newsletter*, the ORI web site, the cover letter accompanying the Annual Report form, and the e-mail network.

## **Introduction**

This report describes the conduct and results of the 2002 Annual Report on Possible Research Misconduct. It presents the regulatory basis for requiring institutions to submit the report, the report results, methodology employed, the follow-up actions taken, the problems encountered, and proposed solutions.

## **Requirements of Federal Regulation**

The PHS regulation (42 CFR Part 50, Subpart A) on misconduct in science places several requirements on institutions receiving or applying for funds under the PHS Act. The institutional requirements are monitored by ORI's Assurance Program.

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant: (1) Has established an administrative process that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart."

Section 50.103(b) of the regulation states: "(1) The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary . . . and updated annually thereafter . . . (2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

To fulfill this requirement, institutions must submit to ORI an Annual Report on Possible Research Misconduct (PHS form #6349).

In administering the Assurance Program, ORI determines whether an institution has a current assurance on file so that PHS funds may be awarded, and reviews the information submitted on the Annual Report form to see whether the institution is complying with the regulation.

## **Results/Methodology**

This section describes the results and methodology of the 2002 Annual Report under the following headings: (1) Electronic Reporting System; (2) Misconduct Activities Reported; (3) Availability of Policies and Procedures; (4) Data Collection; (5) Response Rate; and (6) Changes in Institutional Population.

### **Electronic Reporting System**

The 2002 reporting year was the third year for the ORI electronic Internet-based system, which allowed institutions to access their ORI assurance record for the purpose of updating institutional contact information and to electronically submit their annual report.

Prior to the 2000 annual report, ORI prepared and mailed a hard copy of the annual report, with instructions, to all institutions with active assurances. The electronic system is designed to allow institutions to access and update their institutional assurance record at any time during the year, and to permit institutions to complete their Annual Report on-line during the reporting period. The ORI assurance database can be automatically updated with the information submitted. In implementing this electronic system, ORI eliminated (1) the need to prepare and mail a hard copy report to all active institutions, and (2) the burden of updating each record with the information returned with the annual report. The system also reduced the burden on reporting institutions by providing them with a straightforward on-line reporting system that eliminated the need to prepare and return a hard copy of the annual report.

Over the past 4 years, ORI developed an e-mail network to disseminate information on ORI programs quickly and easily through the e-mail system. This e-mail network was also used as the primary means of notifying institutions of the new electronic annual reporting system. ORI requested and received e-mail addresses on approximately 98 percent of the institutions in the ORI assurance database. To ensure that all institutions were informed of the new reporting system, facsimiles were sent to the remaining institutions that had not previously provided an e-mail address to ORI, as well as to those institutions whose current e-mail address in ORI's records was found to be incorrect. A small number of reports were mailed, via USPS, due to an invalid fax numbers and e-mail addresses.

Consistent with previous years, ORI sent an initial e-mail to institutions on January 15, 2003, notifying them of the requirement to submit an annual report to ORI, and instructions on accessing both their assurance record and the on-line instructions for completing the report. To ensure that all organizations were notified, instructions were also sent via facsimile to the approximately 2 percent of the organizations that had not previously provided ORI with a valid e-mail address. Twenty-six institutions had not provided either a valid e-mail address or a facsimile number to ORI. Annual reports were mailed to these institutions. Of the 4,111 initial e-mail notices that were sent on January 15, 2003, 74 were returned to ORI as non-deliverable, requiring the preparation and transmission of facsimiles to each of these institutions with the annual report instructions. An additional 16 institutional records, requiring the submission of an annual report, were added during the reporting period.

Also consistent with past practices, a second e-mail notice was sent in mid-February to all organizations that had not yet submitted their 2002 Annual Report.

At the March 1, 2003, due date, it was noted that the response rates for the submission of the 2002 Annual Report was less than in previous years. The due date was therefore extended to March 31, 2003, and all institutions were notified via e-mail. A final notice was sent by e-mail on March 19, 2003, to those institutions that had not yet submitted their annual report.

In analyzing the assurance database after the March 31, 2003, deadline, it was noted that a number of institutions had logged on to the system and made changes to their institutional profile, but had not submitted the annual report. Recognizing that this was likely an oversight on

the part of these institutions, e-mail notices were sent to officials at 53 organizations with instructions on manually submitting the annual report to ORI.

## Misconduct Activities Reported

In 2002, 99 institutions reported misconduct activities—the receipt of an allegation or conduct of an inquiry and/or investigation. Seventy-one institutions opened 83 misconduct cases in 2002 upon receipt of new allegations, 44 institutions were continuing to process allegations made in 2001, and 16 institutions were responding to allegations made both prior to and during 2002. The level of reported misconduct activity increased for the fourth consecutive year. See Table 1. Of the 71 institutions reporting new allegations in 2002, 50 were institutions of higher education, 7 were research organizations, 6 were independent hospitals, 5 were health organization, and 3 were small businesses.

<i><b>Table 1: Number of Institutions Reporting Misconduct Activities, Number of Institutions Reporting New Allegations, and Number of New Cases Opened, 1998-2002.</b></i>			
Annual Report	# of Institutions Reporting Activity	# of Institutions - New Allegations	# of New Cases Opened
2002	99	71	83
2001	78	61	72
2000	82	60	62
1999	72	46	63
1998	67	41	54

In their submissions, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

For 2002, institutions reported receiving 163 allegations. The number of allegations for all categories increased from 2001. See Table 2.

**Table 2: Types of Misconduct and Total Number of New Allegations Reported, 1998-2002.**

Annual Report	Fabrication	Falsification	Plagiarism	Other	Total
2002	45	58	27	33	163
2001	37	46	17	27	127
2000	37	24	19	23	103
1999	21	37	13	18	89
1998	15	22	10	22	69

The 83 new cases opened by the institutions in 2002 resulted in 67 inquiries and 31 investigations. Some cases were closed following a preliminary assessment of the allegation or were received too late in the year to begin an inquiry that year. The number of inquiries conducted remained the same as 2001, while the number of investigations was the highest since 1998. See Table 3.

**Table 3: Number of Inquiries and Investigations Conducted in Response to New Allegations, 1998-2002.**

Annual Report	Inquiries	Investigations
2002	67	31
2001	67	20
2000	59	18
1999	51	9
1998	38	7

The 99 institutions reporting misconduct activity conducted a total of 110 inquiries and 63 investigations in 2002. These were in response to allegations made in 2002 and earlier. The number of inquiries conducted by an institution ranged from zero to three. The number of investigations conducted by an institution ranged from zero to two.

### **Availability of Policies and Procedures**

Ninety-seven percent (3,472) of the responding institutions indicated that they had the required policies for handling allegations of scientific misconduct. One hundred and fourteen institutions (3 percent) indicated that they did not have the required policies. However, 55 of the institutions reporting that they did not have a policy had previously submitted a misconduct policy to ORI.

## Data Collection

On January 15, 2003, notifications were sent to 4,111 institutions, including 280 foreign institutions that had an assurance on file with ORI as of December 31, 2002, informing them of their obligation to submit the 2002 Annual Report to ORI. A second notification was sent on February 19, 2003. During this reporting period, notification was sent to an additional 16 institutions that requested to re-establish their expired misconduct assurance by submitting the reports for calendar years 2001 & 2002. Table 4 shows that more than 53 percent of the forms went to small businesses; 37 percent went to organizations most likely to conduct research (codes 10, 20, 30), and the approximate 10 percent remaining went to miscellaneous organizations.

**Table 4: Number of 2002 Annual Report Forms Mailed by Code and Type of Institution.**

Code	Type of Institution	Number	Percent
10	Higher education	905	22.0
20	Research org., institute, lab, foundation	325	7.9
30	Independent hospital	276	6.6
40	Educational org. other than higher education	21	0.5
50	Other health, human resources, environ. orgs.	411	10.0
90	Other (small business)	2,189	53.0
<b>Total</b>		<b>4,127</b>	<b>100</b>

## Response Rate

Eighty-four percent (3,475) of the Annual Reports were submitted by the final deadline. The previous Annual Report survey resulted in a response rate of 82 percent by the March 31, 2001, deadline. Institutions submitted 64 percent (2,638) of the Annual Reports by the March 1, 2003, initial deadline. With the second notification, an additional 837 (20 percent) Annual Reports were submitted by March 31.

## Changes in Institutional Population

As of March 31, 2003, the assurances of 652 institutions were inactivated, including those for 595 institutions that did not submit their Annual Reports and 57 were removed from the ORI database because the institutions did not expect to apply for PHS funds, went out of business, merged with another institution, or did not submit their misconduct policies as requested. Small businesses accounted for approximately 62 percent of the assurances inactivated for not returning their Annual Report or voluntarily withdrawing their assurance. Institutions of higher education accounted for approximately 14 percent of the assurances inactivated. See table 5.

**Table 5: Inactivation of Assurances by Institutional Code and Type and Cause, 2002.**

<b>Code</b>	<b>Institutional Type</b>	<b>No Report Submitted</b>	<b>Voluntary Withdrawal</b>	<b>Total</b>
10	Higher Education	86 (14.5 %)	3 (5.3 %)	89 (13.7 %)
20	Research Org., Institute, Lab, Foundation	42 (7.1 %)	2 (3.5 %)	44 (6.7 %)
30	Independent Hospital	33 (5.5 %)	3 (5.3 %)	36 (5.5 %)
40	Educational Org., Other than Higher Education	3 (0.5 %)	1 (1.7 %)	4 (0.6 %)
50	Other Health, Human Res., Environmental Org.	66 (11.1 %)	7 (12.3 %)	73 (11.2 %)
90	Other (small businesses)	365 (61.3 %)	41 (71.9 %)	406 (62.3 %)
<b>Total</b>		<b>595 (100%)</b>	<b>57 (100%)</b>	<b>652 (100%)</b>

The inactivation of 652 assurances did not produce dramatic changes in the institutional population in the ORI Assurance Database. However, there were small percentage shifts among the types of organizations that comprise the total population. Rank order by size remained the same. See Table 6.

**Table 6: ORI Assurance Database by Code, Type of Institution, Number of Institutions, Percent of Total, and Percent Change from 2001.**

<b>Code</b>	<b>Type of Institution</b>	<b>Number</b>	<b>Per-cent</b>	<b>% Change from 2001</b>
10	Higher education	907	21.9	- 0.1
20	Research org., institute, lab, foundation	326	7.9	0.0
30	Independent hospital	276	6.7	- 0.1
40	Education org. other than higher ed.	21	0.5	0.0
50	Other health, human res., environ. org.	411	9.9	+ 0.2
90	Other (small business)	2,200	53.1	0.0
<b>Total</b>		<b>4,141</b>	<b>100</b>	

The database query for Table 6 is the total number of records (active & inactive) on 3/31/03, and includes the initial assurances (14) processed prior to 4/1/03.



## **Follow-up Actions**

The follow-up actions required by the results of the 2002 Annual Report are described under the following headings: (1) Feedback to Institutions; (2) Requesting Policies and Procedures; (3) Notifying Institutions That They Have Policies; (4) Checking Reporting of Investigations; and (5) Updating Assurance Database.

### **Feedback to Institutions**

This report on the 2002 Annual Report will be posted on the ORI home page and will be available in hard copy upon request. An article will be published in the *ORI Newsletter* in September 2003.

### **Requesting Policies and Procedures for Review**

By the deadline, 114 institutions answered "no" to the question about whether the institution had a policy for responding to allegations of scientific misconduct. However, of this number, 55 institutions had previously submitted misconduct policies to ORI. The 59 institutions, that may not have the required policies, were asked to submit their policies and procedures for review. Additionally, 23 institutions from the top 100 NIH awardee institutions were requested to submit their policy for review.

### **Notifying Institutions That They Have Policies**

The 55 institutions that answered "no" to the question about the availability of an institutional policy will be notified that their institution had previously submitted a policy to ORI. Of this number, 42 have a Small Organization Statement and 13 have a more comprehensive institutional policy.

### **Checking Reporting of Investigations**

The Annual Reports of all institutions that reported misconduct activity were forwarded to the Division of Investigative Oversight (DIO) to check on the reporting of investigations by those institutions. All new activity was properly reported by institutions submitting the 2002 Annual Report.

### **Updating Assurance Database**

The Annual Report results required a major update of the ORI assurance database. By the deadline, 652 institutions had been inactivated.

## **Problems Encountered**

This section describes the problems encountered during the conduct of the 2002 Annual Report survey under the following headings: (1) Electronic system; (2) Response Rate; (3) Erroneous Responses; and (4) Incomplete Reports.

## **Electronic System**

All 2002 annual report notifications were sent using the NIH LISTSERV. During the reporting period, ORI was contacted by many organizations that had questions related to the system or had problems accessing it. In most cases, the issues and questions raised were covered in the instructions, such as the institutions identification number and password. The major problem, however, was that officials failed to keep a record of their "User ID" and/or their "Password" from the previous year. From the original 4,000 institutions ORI received approximately 1,000 - 1,500 e-mail inquiries and another 800 - 1,000 telephone calls. This overwhelming response created a giant backlog on a returned ORI response. Many officials called and left multiple voice-mail messages while also sending e-mail inquiries. Another problem was an issue related to the compatibility of the institution's computer system with the ORI system. While such conflicts are inevitable when dealing with over 4,000 independent systems, the most consistent problem involved difficulties of Macintosh users accessing the system. Also, an issue that was frequently raised concerned the lack of clear acknowledgment once the report had been transmitted to ORI and the incapability of the institution to print a copy of their submitted annual report.

## **Response Rate**

Although the institutions were alerted to the Annual Report survey by the December 2002 *ORI Newsletter* article and by the cover letter accompanying the report form which emphasized the submission deadline, only 64 percent (2,638 of 4,127) of the Annual Reports were received by the March 1 deadline. This is down from the 68 percent received by the same date last year. Another 837 were submitted after the second notification.

## **Erroneous Responses**

The electronic reporting system provided a check box for institutions to indicate whether or not they had a misconduct policy, but the program was designed to default to a "no" answer if the question was not answered. It is evident that some institutions that do have a policy either misunderstood the question, or failed to check the box. The report survey indicated 55 institutions responded that they did not have an institutional policy for responding to allegations of scientific misconduct when, in fact, they had previously submitted a policy to ORI.

## **Incomplete Reports**

The number of incomplete responses is declining. Six institutions which did not report any misconduct activity did not check the box indicating that they did not have any misconduct activity to report. This was a decrease from 11 last year.

## **Proposed Solutions**

Solutions to the problems encountered in the 2002 Annual Report are presented under the following headings: (1) Electronic System; (2) Response Rate; (3) Erroneous Responses; and (4) Incomplete Reports.

### **Electronic System**

ORI is in the process of contracting with a new system designer. The system is to work very similar to the one now in place. The system designer will be asked to adapt the system to provide a printable acknowledgment to the user when the annual report has been successfully transmitted, provide an electronic button that will give the user their password, and the system is to be accessible to Macintosh users. Additionally, all requested information will be required fields. This should eliminate erroneous and incomplete responses.

To avoid confusion for new institutions, ORI started sending “welcome letters” via e-mail in early FY 2003. This letter explains their responsibilities as an awardee institution and it also explains the use of their annual report “User ID” and “Password.”

### **Response Rate**

The major area for improvement is the low response rate of 84 percent by the final deadline. Efforts will be made to improve the accuracy and completeness of the e-mail records within the ORI system. Over the next few years, an effort will be made to raise the initial response rate to 90 percent. While some organizations will choose not to submit their annual reports electronically and will have to receive a hard copy of the annual report, ORI will strive to minimize that number.

Several steps taken previously will continue to be taken to increase the initial response to the 2003 Annual Report survey. An article will be published in the December 2003 issue of the *ORI Newsletter* calling attention to the initial submission deadline and the electronic submission. Detailed instructions and answers to frequently asked questions will be posted on the ORI web site. At a minimum, e-mail reminders regarding the Annual Report due date, will be sent to non-responsive institutions in mid-February and again in mid-March, if necessary.

### **Erroneous Responses**

As indicated previously, institutions that reported they did not have an administrative policy for responding to allegations of scientific misconduct, when they have previously submitted their policy to ORI, will be so notified. When the new electronic system is in place, this task will be done automatically.

### **Incomplete Reports**

Incomplete reports will not be allowed to be submitted with the new system. All requested information will be in fields that require an answer. The instructions will call attention to the question on availability of an administrative policy and will point out that the small organization

statement qualifies as such a policy. The question, however, must be answered before the user can continue.

## **Conclusion**

Once again the Annual Report has demonstrated that it is an essential mechanism for maintaining ORI's compliance and assurance programs. The results of the 2002 Annual Report identified 652 institutions that were inactivated from the assurance database and 59 institutions that may not have the required policies and procedures for handling allegations of scientific misconduct. The survey also collected information on misconduct activities at institutions during the year and the availability of policies to deal with misconduct allegations. Finally, this Report highlights the need for follow-up actions and identifies problems in the reporting process for which solutions are proposed.